

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13545



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UNITED STATES FOOD AND DRUG ADMINISTRATION
CONSUMER COMPLAINT/INJURY REPORT

1. COMPLAINT NUMBER
FLA-9336 **13545**

2. DATE OF COMPLAINT
3/26/99

3. FORM OF COMPLAINT	(1) <input checked="" type="checkbox"/> TELEPHONE (4) <input type="checkbox"/> OTHER (2) <input type="checkbox"/> LETTER (3) <input type="checkbox"/> VISIT	4. SOURCE OF COMPLAINT	<input checked="" type="checkbox"/> CONSUMER <input type="checkbox"/> GOVERNMENT <input type="checkbox"/> LOCAL <input type="checkbox"/> STATE <input type="checkbox"/> FEDERAL	<input type="checkbox"/> TRADE SOURCE <input type="checkbox"/> OTHER
5. COMPLAINANT IDENTIFICATION	b. NAME AND ADDRESS [REDACTED]		d. TELEPHONE NUMBER HOME: [REDACTED] WORK: [REDACTED]	
6. COMPLAINT OR INJURY	a. DESCRIPTION OF COMPLAINT/INJURY Complainant took dietary supplement and drank two alcoholic beverages. Within 5 hours he became confused, very dizzy and drowsy as if "someone slipped him a mickey." He was pulled over by the police and charged with DUI (for which he was later found guilty). He wanted to file a complaint because he feels that the product is not properly labeled to warn consumers against the use of alcohol with the supplement. The incidence occurred back in September 1998. The dietary supplement contained multiple ingredients including: chromium picolinate, barciola carnobgia, cayenne pepper, echinacea, ginko baloba, green tea extract, Ma Huang, selenium, siberian ginseng and white willow bark.			
7. INJURY OR ILLNESS RESULTED	b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT? <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES (If Yes, explain in Remarks)			
(1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES (If "yes" complete items e through d)	e. DE/O/EMOPS (HFC-130) NOTIFIED (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES DATE	f. TYPE SYMPTOM ONSET (HR) (1) <input type="checkbox"/> VOMITING (2) <input type="checkbox"/> NAUSEA (3) <input type="checkbox"/> DIARRHEA (4) <input type="checkbox"/> FEVER (5) <input type="checkbox"/> SKIN/EYE IRR. (6) <input type="checkbox"/> HEADACHE (7) <input checked="" type="checkbox"/> OTHER dizziness 4	g. ATTENDING HEALTH PROFESSIONAL (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES (If "yes", give name, address, phone)	h. HOSPITALIZATION REQUIRED (1) <input type="checkbox"/> NO (2) <input type="checkbox"/> YES (If "yes", give name, address, phone, date)
8. PRODUCT AND LABELING	a. BRAND NAME Synergistic Formulations		b. PRODUCT NAME UDEP - Ultimate Diet Energizer Product	
	c. SIZE AND PACKAGE TYPE 18 caplets in plastic bottle		d. NAME AND LOCATION OF STORE WHERE PURCHASED [REDACTED]	
	e. LOT/SERIAL NUMBER 38572 EXP/USE BY DATE: none		f. DATE PURCHASED 9/1/98	g. PRODUCT USED (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES DATE 9/20/98
9. MANUFACTURER/DISTRIBUTOR OF PRODUCT	a. HOME DISTRICT FLA	c. NAME AND LOCATION OF FIRM Carl Cole 482 Karlo Ct. Deltona, FL 32725 1-800-869-2831		d. IMPORT PRODUCT (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES
10. EVALUATION AND DISPOSITION	a. PROBLEM KEYWORD (1) CODE RX (2) DESCRIPTION Reaction		c. DISPOSITION (1) <input type="checkbox"/> IMMEDIATE FOLLOW-UP (2) <input type="checkbox"/> FOR NEXT EI (3) <input checked="" type="checkbox"/> CLOSED WITHOUT FURTHER INVESTIGATION (4) <input type="checkbox"/> REFERRED TO OTHER FEDERAL AGENCY (5) <input type="checkbox"/> REFERRED TO STATE/LOCAL AGENCY (6) <input type="checkbox"/> REFERRED TO OTHER FDA DISTRICT (7) <input type="checkbox"/> REFERRED TO OCI	
	b. EVALUATION (1) <input type="checkbox"/> NOT AN FDA OBLIGATION (2) <input type="checkbox"/> OBLIGATION, NO VIOLATION (3) <input type="checkbox"/> FDA ACTION INDICATED (4) <input checked="" type="checkbox"/> INSUFFICIENT INFORMATION UNABLE TO EVALUATE		11. PRODUCT CODE 54BCA15	
			12. INFORMATION COPIES TO: <input type="checkbox"/> HFC-130 <input type="checkbox"/> HFD-730 <input type="checkbox"/> HFM-650 <input checked="" type="checkbox"/> HFS-635 <input type="checkbox"/> HPV-210 <input type="checkbox"/> HFZ-630 <input type="checkbox"/> OTHER	

REMARKS

*Forwarded to HFS-635 per IOM instructions
4/12/99 - PRD*

NAME AND TITLE
Karen G. Hirshfield, Investigator

DATE
3/26/99